Complete Summary

GUIDELINE TITLE

Clinical guidelines for the management of anxiety. Management of anxiety panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care.

BIBLIOGRAPHIC SOURCE(S)

McIntosh A, Cohen A, Turnbull N, Esmonde L, Dennis P, Eatock J, Feetam C, Hague J, Hughes I, Kelly J, Kosky N, Lear G, Owens L, Ratcliffe J, Salkovskis P. Clinical guidelines for the management of anxiety. Management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care. London (UK): National Institute for Clinical Excellence (NICE); 2004 Dec. 165 p. [151 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

 On May 12, 2006, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults.

A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant; however, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data

suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated. See the <u>FDA Web site</u> for more information.

• On December 8, 2005, the U.S. Food and Drug Administration (FDA) has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician. See the FDA Web site for more information.

• On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Generalized anxiety disorder and panic disorder (with or without agoraphobia)

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Emergency Medicine Family Practice Internal Medicine Psychiatry Psychology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Occupational Therapists
Patients
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To make recommendations on the management of generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults (aged 18 years and older) in primary, secondary, and community care

TARGET POPULATION

Adults (aged 18 years and older) in primary, secondary and community care with generalised anxiety disorder or panic disorder (with or without agoraphobia)

Note: The guideline does not cover the care of the following: children (people younger than 18 years); people with major depression; people with mixed anxiety and depression; people with bipolar depression; people with seasonal affective disorder (SAD); people with combat disorder; people with anxiety disorders associated with dementia; people with phobic disorders other than panic disorder with agoraphobia; people with organic brain disorders. The guideline also does not cover the care of people with post-traumatic stress disorder or obsessive-compulsive disorder, for which other National Institute for Health and Clinical Excellence (NICE) guidelines are being developed.

INTERVENTIONS AND PRACTICES CONSIDERED

General Management

- 1. Use of appropriate consultation skills and language
- 2. Shared decision-making between patient and healthcare
- 3. Information provision
- 4. Use of appropriate language

Stepped Approach to Care

- 1. Recognition and diagnosis of panic disorder and generalised anxiety disorder (GAD)
 - Use of high standards of consultation skills
 - Use of diagnostic algorithm
 - Patient history
 - Use of screening instruments (not recommended)
- 2. Recognition and treatment of comorbidities, including depression and substance abuse
- 3. Management of patients presenting to Accident and Emergency (A&E)
- 4. Offering treatment in primary care
- 5. Review and consideration of alternative treatments
- 6. Care in specialist mental health services

Psychological Interventions

- 1. Cognitive behavioural therapy (CBT)
- 2. Structured problem solving
- 3. Psychoeducation

Pharmacological Interventions

- 1. Selective serotonin reuptake inhibitors (SSRIs)
 - Paroxetine
 - Fluvoxamine
 - Citalopram
- 2. Tricyclic antidepressants (TCAs)
 - Imipramine
 - Clomipramine
- 3. Benzodiazepines (for GAD only)
 - Diazepam
 - Alprazolam
 - Clonazepam
 - Lorazepam
 - 2-chlordesmethyldiazepam

- 4. Sedating antihistamines (for GAD only)
 - Hydroxyzine
- 5. Selective norepinephrine reuptake Inhibitors (SNRIs)
 - Venlafaxine
- 6. Other agents
 - Buspirone

Self-Help Interventions

- 1. Bibliotherapy
- 2. Support groups
- 3. Exercise
- 4. Cognitive behavioural therapy via a computer interface (CCBT)

Monitoring and Follow-up

- 1. Use of short self-complete questionnaires to monitor outcomes
- 2. Monitoring of medication response and side effects

Intervention/Practices Considered But Not Recommended

Use of questionnaires as screening tools, antipsychotic agents, propranolol, exposure therapy, relaxation training, breathing retraining, eye movement desensitisation and reprocessing (EMDR), psychoanalytic therapy, monoamine oxidase inhibitors (MAOIs), anxiety management training

MAJOR OUTCOMES CONSIDERED

- Degree of improvement in symptoms (clinician and patient reported)
- Anxiety level and incidence of panic attacks
- Side effects of medications
- Incidence of agoraphobic avoidance
- Relapse rate
- Quality of life
- Cost effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Diagnosis

The search strategies attempted to locate meta-analyses, systematic reviews and diagnostic papers for generalised anxiety disorder and panic disorder (with or without agoraphobia). Searches were limited to English language citations.

International Classification of Diseases (ICD) -10 and Diagnostic and Statistical Manual of Mental Disorders (DSM) - IV classifications were used to identify relevant studies. Although in the development process papers considered were limited to those that discussed tools/instruments that could be used as screening and diagnostic tools, rather than instruments that might be used for examining outcomes in studies, the literature search did not impose these limits.

Other papers that might be useful in the process of diagnosis, such as papers that discussed patient or clinician characteristics that might influence prognosis were also searched for.

Interventions

The search strategies attempted to locate meta-analyses, systematic reviews, and randomised controlled trials of interventions for generalised anxiety disorder and panic disorder (with or without agoraphobia). Searches were limited to English language citations.

The search strategies are presented in Appendix 19 of the original guideline document.

Update of Evidence Searches

Due to the delay in publication of the guideline, searches were repeated for MEDLINE and Cochrane Library in November 2004. The search period had a 6-month overlap with previous searches. One thousand, six hundred and eighty one hits were found. The abstracts for these were looked at and the same selection criteria as previously used were applied. Once duplicates and those already included in the guideline (e.g. because of overlapping time period) were excluded, 42 papers remained.

It was considered that nothing was found in the updated searches that necessitated any changes in evidence statements or guideline recommendations.

Health Economics Evidence

The search strategy to identify health economics papers is included in Appendix 19 of the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence from meta-analysis of randomised controlled trials

Ib: Evidence from at least one randomised controlled trial

II a: Evidence from at least one controlled study without randomisation

IIb: Evidence from at least one other type of quasi-experimental study

III: Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVI DENCE

Meta-Analysis Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Sifting and Reviewing the Evidence

Studies retrieved were assessed for their quality and relevance in answering the key clinical questions identified by the guideline development group.

For studies where the Guideline Development Group's (GDG) concern was that of what intervention seemed to be most effective, then in the assessment of those studies the key concern was the quality of the study in terms of the various aspects of study validity. Firstly, if a study credibly demonstrated the causal relationship between treatment and outcome then it was said to have internal validity. Secondly, if the findings could be generalised from the specific study sample to a wider population then it was said to be generalisable or to have external validity. Thirdly, if the study actually measured what it says it measures then it was said to have construct validity.

Outcomes Used

The issue of outcomes in panic disorder and generalised anxiety disorder (GAD) is problematic and often controversial. The following approach was used in the development of this guideline.

Panic Disorder

Outcomes for panic disorder are defined in terms of panic attacks with the primary outcomes to do with changes in panic attacks including

• The number of people per treatment group who did not show a remission in the panic attacks

- The number of people per treatment group who did not show a clinical improvement in the panic attacks
- Number of people reporting panic-related phobias (including agoraphobia and body-sensation phobia)
- Number of people reporting anticipatory anxiety relapse rates among panicfree or symptoms-free patients receiving treatment
- The number of people per treatment group who had any adverse effect (other than deterioration in panic symptoms)
- The average change in the panic symptoms or their severity at the end of the trial

Other outcome measures of interest listed included outcomes concerning comorbidity. Such outcomes were not isolated, as the scope of the review specified non-inclusion of studies concerning comorbid conditions. Otherwise, the third group of outcomes that were recorded is, as with GAD, the acceptability of the treatment. These were measured by the number of people dropping out during the trial. Also measured were suicide attempts, use/misuse of substances, use of health services, and death.

It is also noted that all of the above outcomes are, where possible, grouped according to time periods (short-term: less than three months; medium-term: between three and six months; long-term: more than six months).

Generalised Anxiety Disorder

Generalised anxiety changes at the end of the trial, (including absence of treatment effect or response, improvement rate in the symptoms of GAD on any anxiety scale, group mean score on Hamilton Anxiety scale or other scales as provided by original studies), acceptability of treatment as measured by the number of people dropping out during the trial and post randomisation exclusions; numbers of patients reporting at least one side-effect during the trial; specific side effects, relapse, quality of life measure changes at the end of the treatment.

Synthesising the Evidence

Extraction tables were used to provide the basis for conclusions about the findings of the body of evidence.

Areas Without Evidence

The guideline development group used informal consensus methods to derive evidence statements and recommendations in areas where research literature was not available, drawing upon their clinical knowledge and experience. The research recommendations reflect some of the areas that lacked research evidence that would have been useful in developing recommendations.

Evidence Grading

Once individual papers had been assessed for methodological quality and relevance in terms of the key clinical questions, they were graded according to the levels of evidence. (See "Rating Scheme for the Strength of the Evidence" in this

summary.) This classification is most appropriate for questions of causal relationships and is usually used to assign studies dealing with causal relationships to levels of evidence.

Other types of evidence may, however, have been used in this guideline. In some areas of management, studies looking at causation may not be available or may not be the appropriate study type. Therefore different types of study design will also have been assessed for quality and graded according to the classification outlined, even though the classification is most appropriate for causal relationship studies.

The literature was synthesised, using a qualitative narrative approach, to produce an evidence report. This also included health economics information. This evidence report, with summary evidence statements, was presented to the guideline development group.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The derivation of recommendations involved assessment of evidence, interpretation and consensus to arrive at recommendations. The mix of evidence, interpretation, and consensus varied between topic areas. The grading of recommendations takes this into account and therefore variation may occur between different groups presented with the same evidence. Whilst evidence statements can be formulated without reference to the context in which clinicians practise, this is not always the case with recommendations.

The grading system used was not a mechanistic process where a recommendation derived from an evidence statement with a particular level of evidence had one, and only one, corresponding recommendation grading. The development of recommendations drew upon both the research evidence and expertise of the Guideline Development Group. Therefore a lower strength of recommendation could be given than its evidence level might suggest. Furthermore the available evidence may only partially cover an important clinical area, so again a gap in the evidence would occur. Thus to cover the areas identified by the key clinical questions it is likely that inferences from the available evidence will have to be made, which are beyond the empirical data.

The recommendation grading indicates only the level of evidence upon which it is based. It does not indicate the level of clinical importance or clinical practice relevance.

There may be areas where the group was unable to reach consensus on an area, no matter whether evidence is available or not. Where this may happen, there is scope to report that a consensual recommendation could not be reached, to present the opposing views, and leaving the final view to the user of the

guidelines. Consensus was achieved on all recommendations presented in the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades

Grade A - Directly based on category I evidence

Grade B - Directly based on category II evidence, or extrapolated recommendation from category I evidence

Grade C - Directly based on category III evidence, or extrapolated recommendation from category I or II evidence

Grade D - Directly based on category IV evidence or extrapolated recommendation from category I II or III evidence

NICE 2002 - Evidence from National Institute for Health and Clinical Excellence (NICE) health technology appraisal

COST ANALYSIS

Health Economic Review and Analysis

From a health economics perspective the available evidence relating to the cost effectiveness of pharmacological and/or non-pharmacological treatments for generalised anxiety disorder or panic disorder is scant. The majority of studies which have been undertaken to assess cost effectiveness issues in this area suffer from methodological weaknesses in that these studies have been undertaken upon small numbers of patients and often not in a randomised controlled trial (RCT) or controlled before-and-after study format. Given the paucity and general poor quality of available evidence from a health economics perspective it was decided that it would not be possible to undertake an economic modelling exercise as a component of this guideline.

The literature relating to cost effectiveness has been reviewed and considered under three main headings:

- 1. Studies relating to the cost effectiveness of pharmacological agents
- 2. Studies relating to the cost effectiveness of non-pharmacological agents
- 3. Studies relating to the costs of cognitive behavioural therapy (CBT)

These reviews have been included in the relevant sections of the guideline where effectiveness of the interventions has been discussed. The evidence tables for the health economics studies are presented in Appendix 12 of the full version of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

- 1. The first draft of the guideline (The full guideline, National Institute for Health and Clinical Excellence [NICE] guideline, and Quick Reference Guide) were consulted with Stakeholders, and comments were considered by the Guideline Development Group (GDG).
- 2. The final consultation draft of the Full guideline, the NICE guideline, and the Information for the Public were submitted to stakeholders for final comments, and was also available on the NICE Web site so that any organisation or individual could provide comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grading of recommendations (A-D and NICE 2002) are defined at the end of the "Major Recommendations" field.

Diagnosis and Decision Making

Recognition and Diagnosis of Panic Disorder and Generalised Anxiety Disorder

Consultation Skills

D - All healthcare professionals involved in diagnosis and management should have a demonstrably high standard of consultation skills so that a structured approach can be taken to the diagnosis and subsequent management plan for panic disorder and generalised anxiety disorder. The standards detailed in the video workbook Summative Assessment For General Practice Training: Assessment Of Consulting Skills - the Member of the Royal College of General Practitioners (MRCGP)/Summative Assessment Single Route (see www.rcgp.org.uk/exam) and required of the Membership of the Royal College of General Practitioners are a good example of standards for consulting skills.

Diagnosis

The accurate diagnosis of panic disorder or generalised anxiety disorder is central to the effective management of these conditions. It is acknowledged that frequently there are other conditions present, such as depression, that can make the presentation and diagnosis confusing. An algorithm has been developed to aid the clinician in the diagnostic process, and to identify which guideline is most appropriate to support the clinician in the management of the individual patient.

- D The diagnostic process should elicit necessary relevant information such as personal history, any self medication, and cultural or other individual characteristics that may be important considerations in subsequent care.
- D There is insufficient evidence on which to recommend a well-validated, self-reporting screening instrument to use in the diagnostic process, and so consultation skills should be relied upon to elicit all necessary information.

Comorbidities

- D The clinician should be alert to the common clinical situation of comorbidity, in particular, anxiety with depression and anxiety with substance abuse.
- D The main problem(s) to be treated should be identified through a process of discussion with the patient. In determining the priorities of the comorbidities, the sequencing of the problems should be clarified. This can be helped by drawing up a timeline to identify when the various problems developed. By understanding when the symptoms developed, a better understanding of the relative priorities of the comorbidities can be achieved, and there is a better opportunity of developing an effective intervention that fits the needs of the individual.
- D When the patient has depression or anxiety with depression, the National Institute for Health and Clinical Excellence (NICE) guideline on management of depression should be followed.

Presentation in Accident and Emergency (A&E) with Panic Attacks

It is important to remember that a panic attack does not necessarily constitute a panic disorder, and appropriate treatment of a panic attack may limit the development of panic disorder. For people who present with chest pain at A&E services, there appears to be a greater likelihood of the cause being panic disorder if coronary artery disease is not present or the patient is female or relatively young. Two other variables, atypical chest pain and self-reported anxiety, may also be associated with panic disorder presentations, but there is insufficient evidence to establish a relationship.

- D If a patient presents in A&E, or other settings, with a panic attack, they should:
- Be asked if they are already receiving treatment for panic disorder
- Undergo the minimum investigations necessary to exclude acute physical problems
- Not usually be admitted to a medical or psychiatric bed
- Be referred to primary care for subsequent care, even if assessment has been undertaken in A&E
- Be given appropriate written information about panic attacks and why they are being referred to primary care
- Be offered appropriate written information about sources of support, including local and national voluntary and self-help groups

Shared Decision-Making and Information Provision

People who have panic disorder or generalised anxiety disorder and their carers need comprehensive information, presented in clear and understandable language, about the nature of their condition and the treatment options available. Such information is essential for shared decision-making between patients and healthcare professionals, particularly when making choices between broadly equivalent treatments. In addition, given the emotional, social, and economic costs that generalised anxiety disorder or panic disorder usually entail, patients and their families may need help in contacting support and self-help groups. Support groups can also promote understanding and collaboration between patients, their carers, and healthcare professionals at all levels of primary and secondary care.

- C Shared decision-making should take place as it improves concordance and clinical outcomes.
- D Shared decision-making between the individual and healthcare professionals should take place during the process of diagnosis and in all phases of care.
- D Patients and, when appropriate, families and carers should be provided with information on the nature, course, and treatment of panic disorder or generalised anxiety disorder, including information on the use and likely side-effect profile of medication.
- D To facilitate shared decision-making, evidence-based information about treatments should be available and discussion of the possible options should take place.
- D Patient preference and the experience and outcome of previous treatment(s) should be considered in determining the choice of treatment.
- D Common concerns about taking medication, such as fears of addiction, should be addressed.
- D In addition to being provided with high-quality information, patients, families, and carers should be informed of self-help groups and support groups and be encouraged to participate in such programmes where appropriate.

Language

- D When talking to patients and carers, healthcare professionals should use everyday, jargon free language. If technical terms are used, they should be explained to the patient.
- D Where appropriate, all services should provide written material in the language of the patient, and appropriate interpreters should be sought for people whose preferred language is not English.
- D Where available, consideration should be given to providing psychotherapies in the patient's own language if this is not English.

Screening Tools

D - There is insufficient evidence on which to recommend a well-validated, self-reporting screening instrument to use in the diagnostic process, and so consultation skills should be relied upon to elicit all necessary information.

Care of People with Panic Disorder

- Step 1: Recognition and Diagnosis of Panic Disorder (see above)
- Step 2: Offer Treatment in Primary Care

The recommended treatment options have an evidence base: psychological therapy, medication, and self-help have all been shown to be effective. The choice of treatment will be a consequence of the assessment process and shared decision-making.

There may be instances when the most effective intervention is not available (for example, cognitive behavioural therapy [CBT]) or is not the treatment option chosen by the patient. In these cases, the healthcare professional will need to consider, after discussion with the patient, whether it is acceptable to offer one of the other recommended treatments. If the preferred treatment option is currently unavailable, the healthcare professional will also have to consider whether it is likely to become available within a useful timeframe.

- A Benzodiazepines are associated with a less good outcome in the long term and should not be prescribed for the treatment of individuals with panic disorder.
- D Sedating antihistamines or antipsychotics should not be prescribed for the treatment of panic disorder.
- A In the care of individuals with panic disorder, any of the following types of intervention should be offered and the preference of the person should be taken into account. The interventions that have evidence for the longest duration of effect, in descending order are:
- Psychological therapy
- Pharmacological therapy (antidepressant medication)
- Self-help
- D The treatment option of choice should be available promptly.
- D There are positive advantages of services based in primary care (for example, lower rates of people who do not attend) and these services are often preferred by patients.

Psychological Interventions

- A Cognitive behavioural therapy (CBT) should be used.
- A CBT should be delivered only by suitably trained and supervised people who can demonstrate that they adhere closely to empirically grounded treatment protocols.

- A CBT in the optimal range of duration (7-14 hours in total) should be offered.
- B For most people, CBT should take the form of weekly sessions of 1-2 hours and should be completed within a maximum of 4 months of commencement.
- A Briefer CBT should be supplemented with appropriate focussed information and tasks.
- D Where briefer CBT is used, it should be around 7 hours and designed to integrate with structured self-help materials.
- C For a few people, more intensive CBT over a very short period of time might be appropriate.

Pharmacological Interventions

- D The following must be taken into account when deciding which medication to offer:
- The age of the patient
- Previous treatment response
- Risks
 - The likelihood of accidental overdose by the person being treated and by other family members if appropriate
 - The likelihood of deliberate self-harm, by overdose or otherwise
- Tolerability
- The preference of the person being treated
- Cost, where equal effectiveness is demonstrated
- C All patients who are prescribed antidepressants should be informed, at the time that treatment is initiated, of potential side effects (including transient increase in anxiety at the start of treatment) and of the risk of discontinuation/withdrawal symptoms if the treatment is stopped abruptly or in some instances if a dose is missed or, occasionally, on reducing the dose of the drug.
- D Patients started on antidepressants should be informed about the delay in onset of effect, the time course of treatment, the need to take medication as prescribed, and possible discontinuation/withdrawal symptoms. Written information appropriate to the patient's needs should be made available.
- A Unless otherwise indicated, a selective serotonin reuptake inhibitor (SSRI) licensed for panic disorder should be offered.
- A If an SSRI is not suitable or there is no improvement after a 12-week course and if a further medication is appropriate, imipramine or clomipramine (which are not licensed for panic disorder but have been shown to be effective in its management) may be considered.

When prescribing an antidepressant, the healthcare professional should consider the following:

- D Side effects on the initiation of antidepressants may be minimised by starting at a low dose and increasing the dose slowly until a satisfactory therapeutic response is achieved.
- B In some instances, doses at the upper end of the indicated dose range may be necessary and should be offered if needed.
- B Long-term treatment may be necessary for some people and should be offered if needed.
- D If the patient is showing improvement on treatment with an antidepressant, the medication should be continued for at least 6 months after the optimal dose is reached, after which the dose can be tapered.
- D If there is no improvement after a 12-week course, an antidepressant from the alternative class (if another medication is appropriate) or another form of therapy should be offered.
- C Patients should be advised to take their medication as prescribed. This may be particularly important with short half-life medication in order to avoid discontinuation/withdrawal symptoms.
- C Stopping antidepressants abruptly can cause discontinuation/withdrawal symptoms. To minimise the risk of discontinuation/withdrawal symptoms when stopping antidepressants, the dose should be reduced gradually over an extended period of time.
- C All patients prescribed antidepressants should be informed that, although the drugs are not associated with tolerance and craving, discontinuation/withdrawal symptoms may occur on stopping or missing doses or, occasionally, on reducing the dose of the drug. These symptoms are usually mild and self-limiting but occasionally can be severe, particularly if the drug is stopped abruptly.
- D Healthcare professionals should inform patients that the most commonly experienced discontinuation/withdrawal symptoms are dizziness, numbness and tingling, gastrointestinal disturbances (particularly nausea and vomiting), headache, sweating, anxiety, and sleep disturbances.
- D Healthcare professionals should inform patients that they should seek advice from their medical practitioner if they experience significant discontinuation/withdrawal symptoms.
- D If discontinuation/withdrawal symptoms are mild, the practitioner should reassure the patient and monitor symptoms. If severe symptoms are experienced after discontinuing an antidepressant, the practitioner should consider reintroducing it (or prescribing another from the same class that has a longer half-life) and gradually reducing the dose while monitoring symptoms.

Self-help

A - Bibliotherapy based on CBT principles should be offered.

- D Information about support groups, where they are available, should be offered. (Support groups may provide face-to-face meetings, telephone conference support groups [which can be based on CBT principles], or additional information on all aspects of anxiety disorders plus other sources of help.)
- B The benefits of exercise as part of good general health should be discussed with all patients as appropriate.

NICE 2002 - Current research suggests that the delivery of cognitive behavioural therapy via a computer interface (CCBT) may be of value in the management of anxiety and depressive disorders. This evidence is, however, an insufficient basis on which to recommend the general introduction of this technology into the National Health Service (NHS).

Step 3: Review and Offer Alternative Treatment if Appropriate

D - If, after a course of treatment, the clinician and patient agree that there has been no improvement with one type of intervention, the patient should be reassessed and consideration given to trying one of the other types of intervention.

Step 4: Review and Offer Referral From Primary Care if Appropriate

D - In most instances, if there have been two interventions provided (any combination of psychological intervention, medication, or bibliotherapy) and the person still has significant symptoms, then referral to specialist mental health services should be offered.

Step 5: Care in Specialist Mental Health Services

Specialist mental health services should conduct a thorough, holistic reassessment of the individual, their environment, and social circumstances. This reassessment should include evaluation of:

- Previous treatments, including effectiveness and concordance
- Any substance use, including nicotine, alcohol, caffeine, and recreational drugs
- Comorbidities
- Day-to-day functioning
- Social networks
- Continuing chronic stressors
- The role of agoraphobic and other avoidant symptoms
- D A comprehensive risk assessment should be undertaken and an appropriate risk management plan developed.
- D To undertake these evaluations and to develop and share a full formulation, more than one session may be required and should be available.

Care and management should be based on the individual's circumstances and shared decisions made. Options include:

- Treatment of comorbid conditions
- CBT with an experienced therapist if not offered already, including home based CBT if attendance at clinic is difficult
- Structured problem solving
- Full exploration of pharmaco-therapy
- Day support to relieve carers and family members
- Referral for advice, assessment or management to tertiary centres
- D There should be accurate and effective communication between all healthcare professionals involved in the care of any person with panic disorder, and particularly between primary care clinicians (General Practitioner [GP] and teams) and secondary care clinicians (community mental health teams) if there are existing physical health conditions that also require active management.

Monitoring and Follow Up

Psychological Interventions

D - There should be a process within each practice to assess the progress of a person undergoing CBT. The nature of that process should be determined on a case-by-case basis.

Pharmacological Interventions

- D When a new medication is started, the efficacy and side-effects should be reviewed within 2 weeks of starting treatment and again at 4, 6, and 12 weeks. Follow the Summary of Product Characteristics (SPC) with respect to all other monitoring required.
- D At the end of 12 weeks an assessment of the effectiveness of the treatment should be made and a decision made as to whether to continue or consider an alternative intervention.
- D If medication is to be continued beyond 12 weeks, the individual should be reviewed at 8- to 12-week intervals, depending on clinical progress and individual circumstances.

Self-Help Interventions

D - Individuals receiving self-help interventions should be offered contact with primary healthcare professionals, so that progress can be monitored and alternative interventions considered if appropriate. The frequency of such contact should be determined on a case-by-case basis, but is likely to be between every 4 and 8 weeks.

Outcome Measures

D - Short, self-complete questionnaires (such as the panic subscale of the agoraphobic mobility inventory for individuals with panic disorder) should be used to monitor outcomes wherever possible.

Interventions for Panic Disorder

Pharmacological Compared with Psychological Compared with Combination Interventions for Panic Disorder

- A In the care of individuals with panic disorder, any of the following types of intervention should be offered and the preference of the person should be taken into account. The interventions that have evidence for the longest duration of effect, in descending order are:
- Psychological therapy
- Pharmacological therapy (antidepressant medication)
- Self-help
- D The treatment option of choice should be available promptly.
- D There are positive advantages of services based in primary care (for example, lower rates of people who do not attend) and these services are often preferred by patients.

Pharmacological Interventions for Panic Disorder

- A Benzodiazepines are associated with a less good outcome in the long term and should not be prescribed for the treatment of individuals with panic disorder.
- D Sedating antihistamines or antipsychotics should not be prescribed for the treatment of panic disorder.
- D The following must be taken into account when deciding which medication to offer:
- The age of the patient
- Previous treatment response
- Risks
 - The likelihood of accidental overdose by the person being treated and by other family members if appropriate
 - The likelihood of deliberate self-harm, by overdose or otherwise
- Tolerability
- The preference of the person being treated
- Cost, where equal effectiveness is demonstrated
- C All patients who are prescribed antidepressants should be informed, at the time that treatment is initiated, of potential side effects (including transient increase in anxiety at the start of treatment) and of the risk of discontinuation/withdrawal symptoms if the treatment is stopped abruptly or in some instances if a dose is missed or, occasionally, on reducing the dose of the drug.
- D Patients started on antidepressants should be informed about the delay in onset of effect, the time course of treatment, the need to take medication as

prescribed, and possible discontinuation/withdrawal symptoms. Written information appropriate to the patient's needs should be made available.

- A Unless otherwise indicated, an SSRI licensed for panic disorder should be offered.
- A If an SSRI is not suitable or there is no improvement after a 12-week course and if a further medication is appropriate, imipramine or clomipramine (which are not licensed for panic disorder but have been shown to be effective in its management) may be considered.

When prescribing an antidepressant, the healthcare professional should consider the following:

- D Side effects on the initiation of antidepressants may be minimised by starting at a low dose and increasing the dose slowly until a satisfactory therapeutic response is achieved.
- B In some instances, doses at the upper end of the indicated dose range may be necessary and should be offered if needed.
- B Long-term treatment may be necessary for some people and should be offered if needed.
- D If the patient is showing improvement on treatment with an antidepressant, the medication should be continued for at least 6 months after the optimal dose is reached, after which the dose can be tapered.
- D If there is no improvement after a 12-week course, an antidepressant from the alternative class (if another medication is appropriate) or another form of therapy should be offered.
- C Patients should be advised to take their medication as prescribed. This may be particularly important with short half-life medication in order to avoid discontinuation/withdrawal symptoms.
- C Stopping antidepressants abruptly can cause discontinuation/withdrawal symptoms. To minimise the risk of discontinuation/withdrawal symptoms when stopping antidepressants, the dose should be reduced gradually over an extended period of time.
- C All patients prescribed antidepressants should be informed that, although the drugs are not associated with tolerance and craving, discontinuation/withdrawal symptoms may occur on stopping or missing doses or, occasionally, on reducing the dose of the drug. These symptoms are usually mild and self-limiting but occasionally can be severe, particularly if the drug is stopped abruptly.
- D Healthcare professionals should inform patients that the most commonly experienced discontinuation/withdrawal symptoms are dizziness, numbness and tingling, gastrointestinal disturbances (particularly nausea and vomiting), headache, sweating, anxiety, and sleep disturbances.

- D Healthcare professionals should inform patients that they should seek advice from their medical practitioner if they experience significant discontinuation/withdrawal symptoms.
- D If discontinuation/withdrawal symptoms are mild, the practitioner should reassure the patient and monitor symptoms. If severe symptoms are experienced after discontinuing an antidepressant, the practitioner should consider reintroducing it (or prescribing another from the same class that has a longer half-life) and gradually reducing the dose while monitoring symptoms.

Psychological Interventions for Panic Disorder

- A CBT should be used.
- A CBT should be delivered only by suitably trained and supervised people who can demonstrate that they adhere closely to empirically grounded treatment protocols.
- A CBT in the optimal range of duration (7-14 hours in total) should be offered.
- B For most people, CBT should take the form of weekly sessions of 1-2 hours and should be completed within a maximum of 4 months of commencement.
- A Briefer CBT should be supplemented with appropriate focussed information and tasks.
- D Where briefer CBT is used, it should be around 7 hours and designed to integrate with structured self-help materials.
- C For a few people, more intensive CBT over a very short period of time might be appropriate.

Other Interventions for Panic Disorder

- A Bibliotherapy based on CBT principles should be offered.
- D Information about support groups, where they are available, should be offered. (Support groups may provide face-to-face meetings, telephone conference support groups [which can be based on CBT principles], or additional information on all aspects of anxiety disorders plus other sources of help.)
- $\ensuremath{\mathsf{B}}$ The benefits of exercise as part of good general health should be discussed with all patients as appropriate.

NICE 2002 - Current research suggests that the delivery of cognitive behavioural therapy via a computer interface (CCBT) may be of value in the management of anxiety and depressive disorders. This evidence is, however, an insufficient basis on which to recommend the general introduction of this technology into the NHS.

Care of People with Generalised Anxiety Disorder

Step 1: Recognition and Diagnosis of Generalised Anxiety Disorder (as panic disorder, see above)

Step 2: Offer Treatment in Primary Care

The recommended treatment options have an evidence base: psychological therapy, medication, and self-help have all been shown to be effective. The choice of treatment will be a consequence of the assessment process and shared decision-making.

There may be instances when the most effective intervention is not available (for example, cognitive behavioural therapy [CBT]) or is not the treatment option chosen by the patient. In these cases, the healthcare professional will need to consider, after discussion with the patient, whether it is acceptable to offer one of the other recommended treatments. If the preferred treatment option is currently unavailable, the healthcare professional will also have to consider whether it is likely to become available within a useful timeframe.

If immediate management of generalised anxiety disorder is necessary, any or all of the following should be considered:

- D Support and information
- C Problem solving
- A Benzodiazepines
- A Sedating antihistamines
- D Self help
- B Benzodiazepines should not usually be used beyond 2 to 4 weeks.
- A In the longer-term care of individuals with generalised anxiety disorder, any of the following types of intervention should be offered and the preference of the person with generalised anxiety disorder should be taken into account. The interventions that have evidence for the longest duration of effect, in descending order are:
- Psychological therapy
- Pharmacological therapy (antidepressant medication)
- Self-help
- D The treatment option of choice should be available promptly.
- D There are positive advantages of services based in primary care (for example, lower rates of people who do not attend) and these services are often preferred by patients.

Psychological Interventions

A - CBT should be used.

- A CBT should be delivered only by suitably trained and supervised people who can demonstrate that they adhere closely to empirically grounded treatment protocols.
- A CBT in the optimal range of duration (16-20 hours in total) should be offered.
- B For most people, CBT should take the form of weekly sessions of 1-2 hours and should be completed within a maximum of 4 months of commencement.
- A Briefer CBT should be supplemented with appropriate focussed information and tasks.
- D Where briefer CBT is used, it should be around 8-10 hours and be designed to integrate with structured self-help materials.

Pharmacological Interventions

- D The following must be taken into account when deciding which medication to offer:
- The age of the patient
- Previous treatment response
- Risks
 - The likelihood of accidental overdose by the person being treated and by other family members if appropriate
 - The likelihood of deliberate self harm, by overdose or otherwise
- Tolerability
- The preference of the person being treated
- Cost, where equal effectiveness is demonstrated
- C All patients who are prescribed antidepressants should be informed, at the time that treatment is initiated, of potential side effects (including transient increase in anxiety at the start of treatment) and of the risk of discontinuation/withdrawal symptoms if the treatment is stopped abruptly or in some instances if a dose is missed or, occasionally, on reducing the dose of the drug.
- D Patients started on antidepressants should be informed about the delay in onset of effect, the time course of treatment, the need to take medication as prescribed, and possible discontinuation/withdrawal symptoms. Written information appropriate to the patient's needs should be made available.
- B Unless otherwise indicated, an SSRI should be offered.
- D If one SSRI is not suitable or there is no improvement after a 12-week course, and if a further medication is appropriate, another SSRI should be offered.

When prescribing an antidepressant, the healthcare professional should consider the following:

- D Side effects on the initiation of antidepressants may be minimised by starting at a low dose and increasing the dose slowly until a satisfactory therapeutic response is achieved.
- B In some instances, doses at the upper end of the indicated dosage range may be necessary and should be offered if needed.
- B Long-term treatment may be necessary for some people and should be offered if needed.
- D If the patient is showing improvement on treatment with an antidepressant, the drug should be continued for at least 6 months after the optimal dose is reached, after which the dose can be tapered.
- D If there is no improvement after a 12-week course, another SSRI (if another medication is appropriate) or another form of therapy should be offered.
- C Patients should be advised to take their medication as prescribed. This may be particularly important with short half-life medication in order to avoid discontinuation/withdrawal symptoms.
- C Stopping antidepressants abruptly can cause discontinuation/withdrawal symptoms. To minimise the risk of discontinuation/withdrawal symptoms when stopping antidepressants, the dose should be reduced gradually over an extended period of time.
- C All patients prescribed antidepressants should be informed that, although the drugs are not associated with tolerance and craving, discontinuation/withdrawal symptoms may occur on stopping or missing doses or, occasionally, on reducing the dose of the drug. These symptoms are usually mild and self-limiting but occasionally can be severe, particularly if the drug is stopped abruptly.
- D Healthcare professionals should inform patients that the most commonly experienced discontinuation/withdrawal symptoms are dizziness, numbness and tingling, gastrointestinal disturbances (particularly nausea and vomiting), headache, sweating, anxiety and sleep disturbances.
- D Healthcare professionals should inform patients that they should seek advice from their medical practitioner if they experience significant discontinuation/withdrawal symptoms.
- D If discontinuation/withdrawal symptoms are mild, the practitioner should reassure the patient and monitor symptoms. If severe symptoms are experienced after discontinuing an antidepressant, the practitioner should consider reintroducing it (or prescribing another from the same class that has a longer half-life) and gradually reducing the dose while monitoring symptoms.

Self-Help Interventions

- A Bibliotherapy based on CBT principles should be offered.
- D Information about support groups, where they are available, should be offered. (Support groups may provide face-to-face meetings, telephone

conference support groups [which can be based on CBT principles], or additional information on all aspects of anxiety disorders plus other sources of help).

- C Large group CBT should be considered.
- B The benefits of exercise as part of good general health should be discussed with all patients as appropriate.

NICE 2002 - Current research suggests that the delivery of cognitive behavioural therapy via a computer interface (CCBT) may be of value in the management of anxiety and depressive disorders. This evidence is, however, an insufficient basis on which to recommend the general introduction of this technology into the NHS.

Step 3: Review and Offer Alternative Treatment if Appropriate

D - If, following a course of treatment, the clinician and patient agree that there has been no improvement with one type of intervention, the patient should be reassessed and consideration given to trying one of the other types of intervention.

Step 4: Review and Offer Referral from Primary Care if Appropriate

D - In most instances, if there have been two interventions provided (any combination of medication, psychological intervention, or bibliotherapy) and the person still has significant symptoms, then referral to specialist mental health services should be offered.

If venlafaxine is being considered:

- D Venlafaxine treatment should only be initiated by specialist mental health medical practitioners including General Practitioners with a Special Interest in Mental Health.
- D Venlafaxine treatment should only be managed under the supervision of specialist mental health medical practitioners including General Practitioners with a Special Interest in Mental Health.
- A The dose of venlafaxine should be no higher than 75 mg per day.
- D Before prescribing venlafaxine an initial electrocardiogram (ECG) and blood pressure measurement should be undertaken. There should be regular monitoring of blood pressure and monitoring of cardiac status as clinically appropriate.

Step 5: Care in Specialist Mental Health Services

- D Specialist mental health services should conduct a thorough, holistic, reassessment of the individual, their environment and social circumstances. This reassessment should include evaluation of:
- Previous treatments, including effectiveness and concordance

- Any substance use, including nicotine, alcohol, caffeine, and recreational drugs
- Comorbidities
- Day-to-day functioning
- Social networks
- Continuing chronic stressors
- The role of agoraphobic and other avoidant symptoms.

A comprehensive risk assessment should be undertaken and an appropriate risk management plan developed.

- D To undertake these evaluations and to develop and share a full formulation, more than one session may be required and should be available.
- D Care and management will be based on the individual's circumstances and shared decisions arrived at. Options include:
- Treatment of comorbid conditions
- CBT with an experienced therapist if not offered already, including home based CBT if attendance at clinic is problematic
- Structured problem solving
- Full exploration of pharmaco-therapy
- Day support to relieve carers and family members
- Referral for advice, assessment, or management to tertiary centres
- D There should be accurate and effective communication between all healthcare professionals involved in the care of any person with generalised anxiety disorder and particularly between primary care clinicians (GP and teams) and secondary care clinicians (community mental health teams) if there are existing physical health conditions that also require active management.

Monitoring and Follow Up

Psychological Interventions

D - There should be a process within each practice to assess the progress of a person undergoing CBT. The nature of that process should be determined on a case-by-case basis.

Pharmacological Interventions

- D When a new medication is started, the efficacy and side-effects should be reviewed within 2 weeks of starting treatment and again at 4, 6, and 12 weeks. Follow the Summary of Product Characteristics (SPC) with respect to all other monitoring required.
- D At the end of 12 weeks, an assessment of the effectiveness of the treatment should be made, and a decision made as to whether to continue or consider an alternative intervention.

D - If medication is to be continued beyond 12 weeks, the individual should be reviewed at 8- to 12- week intervals, depending on clinical progress and individual circumstances.

Self-Help Interventions

D - Individuals receiving self-help interventions should be offered contact with primary healthcare professionals, so that progress can be monitored and alternative interventions considered if appropriate. The frequency of such contact should be determined on a case-by-case basis, but is likely to be between every 4 and 8 weeks.

Outcome Measures

D - Short, self-complete questionnaires (such as the panic subscale of the agoraphobic mobility inventory for individuals with panic disorder) should be used to monitor outcomes wherever possible.

Interventions for Generalised Anxiety Disorder (GAD)

Pharmacological Compared with Psychological Compared with Combined Interventions for GAD

If immediate management of GAD is necessary, any or all of the following should be considered:

- D Support and information
- C Problem solving
- A Benzodiazepines
- A Sedative antihistamines
- D Self help
- B Benzodiazepines should not usually be used beyond 2-4 weeks.
- A In the longer-term care of individuals with generalised anxiety disorder, any of the following types of intervention should be offered and the preference of the person with generalised anxiety disorder should be taken into account. The interventions that have evidence for the longest duration of effect, in descending order are:
- Psychological therapy
- Pharmacological therapy (antidepressant medication)
- Self-help
- D The treatment option of choice should be available promptly.
- D There are positive advantages of services based in primary care (for example, lower rates of people who do not attend) and these services are often preferred by patients.

Pharmacological Interventions for GAD

- D The following must be taken into account when deciding which medication to offer:
- The age of the patient
- Previous treatment response
- Risks
 - The likelihood of accidental overdose by the person being treated and by other family members if appropriate
 - The likelihood of deliberate self harm, by overdose or otherwise
- Tolerability
- The preference of the person being treated
- Cost, where equal effectiveness is demonstrated
- C All patients who are prescribed antidepressants should be informed, at the time that treatment is initiated, of potential side effects (including transient increase in anxiety at the start of treatment) and of the risk of discontinuation/withdrawal symptoms if the treatment is stopped abruptly or in some instances if a dose is missed or, occasionally, on reducing the dose of the drug.
- D Patients started on antidepressants should be informed about the delay in onset of effect, the time course of treatment, the need to take medication as prescribed, and the possible discontinuation/withdrawal symptoms. Written information appropriate to the patient's needs should be made available.
- B Unless otherwise indicated, an SSRI should be offered.
- D If one SSRI is not suitable or there is no improvement after a 12-week course, and if a further medication is appropriate, another SSRI should be offered.

When prescribing an antidepressant, the healthcare professional should consider the following:

- D Side effects on the initiation of antidepressants may be minimised by starting at a low dose and increasing the dose slowly until a satisfactory therapeutic response is achieved.
- B In some instances, doses at the upper end of the indicated dosage range may be necessary and should be offered if needed.
- B Long-term treatment may be necessary for some people and should be offered if needed.
- D If the patient is showing improvement on treatment with an antidepressant, the drug should be continued for at least 6 months after the optimal dose is reached, after which the dose can be tapered.
- D If there is no improvement after a 12-week course, another SSRI (if another medication is appropriate) or another form of therapy should be offered.

- C Patients should be advised to take their medication as prescribed. This may be particularly important with short half-life medication in order to avoid discontinuation/withdrawal symptoms.
- C Stopping antidepressants abruptly can cause discontinuation/withdrawal symptoms. To minimise the risk of discontinuation/withdrawal symptoms when stopping antidepressants, the dose should be reduced gradually over an extended period of time.
- C All patients prescribed antidepressants should be informed that, although the drugs are not associated with tolerance and craving, discontinuation/withdrawal symptoms may occur on stopping or missing doses or, occasionally, on reducing the dose of the drug. These symptoms are usually mild and self-limiting but occasionally can be severe, particularly if the drug is stopped abruptly.
- D Healthcare professionals should inform patients that the most commonly experienced discontinuation/withdrawal symptoms are dizziness, numbness and tingling, gastrointestinal disturbances (particularly nausea and vomiting), headache, sweating, anxiety, and sleep disturbances.
- D Healthcare professionals should inform patients that they should seek advice from their medical practitioner if they experience significant discontinuation/withdrawal symptoms.
- D If discontinuation/withdrawal symptoms are mild, the practitioner should reassure the patient and monitor symptoms. If severe symptoms are experienced after discontinuing an antidepressant, the practitioner should consider reintroducing it (or prescribing another from the same class that has a longer half-life) and gradually reducing the dose while monitoring symptoms.

If venlafaxine is being considered

- D Venlafaxine treatment should only be initiated by specialist mental health medical practitioners including General Practitioners with a Special Interest in Mental Health.
- D Venlafaxine treatment should only be managed under the supervision of specialist mental health medical practitioners including General Practitioners with a Special Interest in Mental Health.
- A The dose of venlafaxine should be no higher than 75 mg per day.
- D Before prescribing venlafaxine an initial ECG and blood pressure measurement should be undertaken. There should be regular monitoring of blood pressure, and monitoring of cardiac status as clinically appropriate.

Psychological Interventions for GAD

A - CBT should be used.

- A CBT should be delivered only by suitably trained and supervised people who can demonstrate that they adhere closely to empirically grounded treatment protocols.
- A CBT in the optimal range of duration (16-20 hours in total) should be offered.
- B For most people, CBT should take the form of weekly sessions of 1-2 hours and should be completed within a maximum of 4 months of commencement.
- A Briefer CBT should be supplemented with appropriate focussed information and tasks.
- D Where briefer CBT is used, it should be around 8-10 hours and be designed to integrate with structured self-help materials.

Other Interventions for GAD

- A Bibliotherapy based on CBT principles should be offered.
- D Information about support groups, where they are available, should be offered. (Support groups may provide face-to-face meetings, telephone conference support groups [which can be based on CBT principles], or additional information on all aspects of anxiety disorders plus other sources of help.)
- C Large group CBT should be considered.
- B The benefits of exercise as part of good general health should be discussed with all patients as appropriate.

NICE 2002 - Current research suggests that the delivery of cognitive behavioural therapy via a computer interface (CCBT) may be of value in the management of anxiety and depressive disorders. This evidence is, however, an insufficient basis on which to recommend the general introduction of this technology into the NHS.

Definitions:

Evidence Categories

Ia: Evidence from meta-analysis of randomised controlled trials

Ib: Evidence from at least one randomised controlled trial

II a: Evidence from at least one controlled study without randomisation

IIb: Evidence from at least one other type of quasi-experimental study

III: Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Recommendation Grades

Grade A - Directly based on category I evidence

Grade B - Directly based on category II evidence, or extrapolated recommendation from category I evidence

Grade C - Directly based on category III evidence, or extrapolated recommendation from category I or II evidence

Grade D - Directly based on category IV evidence or extrapolated recommendation from category I II or III evidence

NICE 2002 - Evidence from NICE health technology appraisal

CLINICAL ALGORITHM(S)

Clinical Algorithms are provided in the full version of the original guideline document for:

- Management of panic disorder in primary care: Steps 2-4
- Management of generalised anxiety disorder in primary care: Steps 2-4

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate and consistent quality of care for patients with generalised anxiety disorder and panic disorder (with or without agoraphobia)

POTENTIAL HARMS

- Antidepressants may result in a transient increase in anxiety at the start of treatment.
- Selective serotonin reuptake inhibitors (SSRIs) may cause nausea, diarrhoea, headache, dizziness, sexual dysfunction, asthenia, somnolence sweating, changes in blood pressure, and myoclonus.
- Potential side effects of buspirone include dizziness, headaches, nausea, nervousness, and paraesthesia.

- Stopping antidepressants abruptly can cause discontinuation/withdrawal symptoms. The most commonly experienced discontinuation/withdrawal symptoms are dizziness, numbness and tingling, gastrointestinal disturbances (particularly nausea and vomiting), headache, sweating, anxiety, and sleep disturbances.
- Tricyclic antidepressants (TCAs) cause, to varying degrees, anticholinergic side effects (dry mouth, blurred vision, constipation, urinary retention, sweating), sedation, and increase in heart rate.
- Serotonin syndrome may develop following co-administration of SSRIs or SSRIs with monoamine oxidase inhibitors (MAOIs) and is potentially life threatening.
- Venlafaxine has a broad range of side effects which can increase blood pressure at higher doses and is associated with a high incidence of discontinuation symptoms.
- Benzodiazepines side effects include fatigue and insomnia.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Guidelines are only one type of information that health care professionals may
 use when making decisions about patient care. It is assumed that this
 guideline, like all guidelines, will be used by health care professionals who will
 also bring to bear their clinical knowledge and judgement in making decisions
 about caring for individual patients. It may not always be appropriate to apply
 either specific recommendations or the general messages in this document to
 each individual or in every circumstance. The availability of resources may
 also influence decisions about patient care, including the adoption of
 recommendations.

When referring to pharmacological treatments, the National Institute for Health and Clinical Excellence (NICE) guidelines will normally recommend use within licensed indications. Exceptionally, and only where the evidence supports it, the guideline may recommend use outside a treatment's licensed indications. In this guideline the tricyclic antidepressant, imipramine, was considered to be a pharmacological intervention that although not licensed for panic disorder should be considered. The Guideline Development Group did therefore look at the research literature for this preparation and made recommendations about its use in panic disorder. The decision to examine imipramine was also influenced by the consideration that it was a drug that had been available before current licensing practices existed and was considered by some Guideline Development Group members to be used in clinical practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Resource Implications

Local health communities should review their existing practice in the treatment and management of panic disorder and generalised anxiety disorder against this guideline. The review should consider the resources required to implement the recommendations set out in the original guideline document, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways, and protocols should be reviewed in the light of this guidance and revised accordingly.

General

The implementation of this guideline will build on the National Service Frameworks for Mental Health in England and Wales and should form part of the service development plans for each local health community in England and Wales. The National Service Frameworks are available for England from http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/MentalHealth/fs/en, and for Wales from www.wales.nhs.uk/sites/home.cfm?orgid=438. The National Institute for Mental Health in England (NIMHE), which is part of the National Health Service (NHS) Modernisation Agency, is able to support the implementation of National Institute for Health and Clinical Excellence (NICE) guidelines through its regional development centres. More details can be found at www.nimhe.org.uk.

The introduction of the new general medical services (GMS) contract for primary care on 1 April 2004 provides a further opportunity to implement these guidelines. A draft quality and outcome framework (QOF) is provided as part of the Audit section (see Appendix D of the NICE version of the original guideline document).

This guideline should be used in conjunction with the NICE guidance detailed in the section 6 of the NICE version of the original guideline document.

Audit

Suggested audit criteria are listed in Section 11 of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice. A draft quality and outcome framework is provided (see Section 11 of the original guideline document). This new framework is not part of the standard GMS contract, but could be used by Personal Medical Services practices if they wish.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Clinical Algorithm Patient Resources Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

McIntosh A, Cohen A, Turnbull N, Esmonde L, Dennis P, Eatock J, Feetam C, Hague J, Hughes I, Kelly J, Kosky N, Lear G, Owens L, Ratcliffe J, Salkovskis P. Clinical guidelines for the management of anxiety. Management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care. London (UK): National Institute for Clinical Excellence (NICE); 2004 Dec. 165 p. [151 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Dec

GUI DELI NE DEVELOPER(S)

National Collaborating Centre for Primary Care - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Alan Cohen (Chair) Director of Primary Care, Sainsbury Centre for Mental Health, London; Paul Dennis, Nurse Practitioner in Mental Health, Meadows Health Centre, Nottingham; Revd John Eatock, Senior Counsellor, Bolton, Salford & Trafford Mental Health Partnership & ead Advisor, British Association for Counselling and Psychotherapy; Lisa G Esmonde (December 2002-September 2003) Research Associate, ScHARR, University of Sheffield; Celia Feetam, Clinical Psychiatric Pharmacist, Aston University and Birmingham and Solihull, Mental Health Trust; Dr John Hague, General Practitioner and Mental Health Lead, Ipswich Primary Care Trust; Dr Ian Hughes, Consultant Clinical Psychologist, Cardiff & Vale NHS Trust; Julie Kelly, Patient Representative, National Phobics Society; Dr Nick Kosky, Consultant Psychiatrist and Clinical Director, North Dorset Primary Care Trust; Geraldine Lear, Community Psychiatric Nurse, Nottinghamshire Healthcare NHS Trust; Aileen McIntosh, Deputy Director, Sheffield Evidence Based Guidelines Programme, Public Health, ScHARR, University of Sheffield; Lilian Owens, Patient Representative, No Panic; Julie Ratcliffe, Health Economist, Sheffield Health Economics Group, ScHARR, University of Sheffield; Professor Paul Salkovskis, Clinical Director of the Centre for Anxiety Disorders and Trauma, South London and Maudsley NHS Trust, and Professor of Clinical Psychology and Applied Science, Institute of Psychiatry, King's College, London

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

At each Guideline Development Group (GDG) meeting, all GDG members declared any potential conflict of interests.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Primary Care. Anxiety. Management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care. London (UK): National Institute for Clinical Excellence (NICE); 2004 Dec. 52 p. (Clinical guideline; no. 22). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Anxiety: management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary,

secondary and community care. Quick reference guide. National Collaborating Centre for Primary Care, 2004 Dec. 11 p. Available from the <u>National Institute</u> for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N0763. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Section 11 of the <u>original guideline</u> document.

PATIENT RESOURCES

The following is available:

Management of panic disorder and generalised anxiety disorder in adults.
 Understanding NICE guidance - information for people with panic disorder or generalised anxiety disorder, their families and carers, and the public.
 National Institute for Clinical Excellence (NICE), 2004 Dec. 40 p. Available from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref N0764. 11 Strand, London, WC2N 5HR.

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NGC STATUS

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